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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,731	01/03/2001	Lawrence Loomis		1252

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Jonathan E. Grant
2120 L Street, N.W., Suite 210
Washington, DC 20037

EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/24/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/752,731

Applicant(s)

LOOMIS ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

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APPLICANT'S INVENTION

1. Applicant's invention is directed to compositions and uses thereof comprising at least one lytic enzyme and a carrier as set forth in independent claims 1 and 31.

Note: Claims 1-59 are pending.

112 REJECTIONS

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3, 20, 24, 33, 49, 50, and 56-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 33, line 2: The claim as written is ambiguous because it does not end with a 'period'. Thus, it is unclear whether Applicant intended to add additional text.

Claims 20 and 50, lines 4, 9, and 10: The claim as written is confusing because each line contains a 'period'. Thus, it is unclear after which term Applicant intended to conclude the sentence.

Claims 20 and 45, line 10: The claim as written is confusing because it is unclear what Applicant intends by the phrase 'synergistically enhance'. Applicant is respectfully requested to clarify the term and point to page and line numbers in the specification for support of such terminology.

Claim 24, line 4: The sentence is confusing because there is no 'period' to conclude the sentence. In addition, it appears as if the sentence is incomplete.

Claims 49 and 56-59, line 1: The claim as written is ambiguous because it is a method claim that refers back to claim 31 which is a composition claim. Did Applicant intend claim 49 to be a composition claim? Please make the appropriate correction(s).

OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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5. Claims 31-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 09/932,460. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth below. Both applications are directed toward composition claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-4, 6, and 7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-6, 11, 12, 14, 15-17, and 20 of copending Application No. 09/866,106. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth below. Both applications are directed toward method of treating bacterial infections.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 31, 33, and 36-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19, 20, 22-33 of copending Application No. 10/083,142. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth below. Both applications are directed toward composition claims.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-27 and 31-56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of copending Application No. 09/908,737. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth below. Both applications are directed a method of treating bacterial infections and compositions thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 31, 33, and 36-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,423,299. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward bacterial compositions.

10. Claims 31, 33, 36-44, and 56-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-11, and 13-15 of U.S. Patent No. 5,997,862. Although the conflicting claims are not identical,

they are not patentably distinct from each other because both sets of claims are directed toward bacterial compositions.

11. Claims 31, 32, 34, and 56-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-5 of U.S. Patent No. 6,277,399. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward bacterial compositions.

12. Claims 1-3, 15, 16, and 28-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-6, 11, 12, 14, 34, 36, 37, 50, and 51 of US Patent No. 6,238,661. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward methods involving bacterial infections.

13. Claims 1-14, 17-25, 27, and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,264,945. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward bacterial infection methods.

14. Claims 1-5, and 26-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-10, 16, 17, and 20 of U.S. Patent No. 6,056,954. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward methods involving bacterial infections.

15. Claims 31, 32, and 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,406,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward bacterial compositions.

16. Claims 31, 33, and 36-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-16 of U.S. Patent No. 6,017,528. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward bacterial compositions.

17. Claims 31 and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,399,098. Although the conflicting claims are not identical, they are not patentably

distinct from each other because both sets of claims are directed toward bacterial compositions.

18. Claim 31 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,399,097. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward bacterial compositions.

19. Claims 31-34 and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,432,444. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward bacterial compositions.

20. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,254,866. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward methods involving bacterial infections.

21. Claims 1, 3, and 6-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S.

Patent No. 6,326,002. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward methods involving bacterial infections.

22. Claims 1, 3, and 6-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,985,271. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward methods involving bacterial infections.

23. Claims 1, 3, 6-9, 14, 15, and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5-8, and 10-12 of U.S. Patent No. 6,248,324. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward methods involving bacterial infections.

24. Claims 1, 3, 6-16, 20, 31, 33, 38-46, 50, and 56-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5-13, 15-22, and 25-40 of U.S. Patent No. 6,056,955. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward methods involving bacterial infections and compositions thereof.

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Note: In each of the applications/patents cited above, both the composition and/or method claims comprise at least one lytic enzyme and a carrier. Thus, for the composition claims, the claims are obvious over one another because the components are the same regardless of whether Applicant has incorporated a different intended use into the claim preamble or specified desired bacteria or modes of delivery of the carrier. Likewise, the method claims are obvious over one another because they require the same components and are all used for bacterial infections. Some method claims differ in the location of the bacterial infection, type of infection for which the composition is administered or mode of delivery to the bacteria location. In addition, some of the method claims disclose specific bacteria of interest. However, in each of the instances above the same components and/or method steps are required to carry out the methods or for the compositions.

SPECIFICATION

25. Applicant is respectfully requested to update the continuing data appearing in the specification.

COMMENTS/NOTES

26. It should be noted that no prior art was found which anticipates or renders obvious the instant invention. Thus, the claims are allowable over the prior art of record because the prior art neither anticipates nor renders obvious Applicant's invention as

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set forth in the claims. However, Applicant MUST address and overcome the double patenting and 112, second paragraph, rejections as set forth above.

27. Due to the enormous number of co-pending cases directed to compositions and/or methods comprising at least one lytic enzyme and a carrier, Applicant is respectfully requested to submit copies of the pending claims that read on the instant invention in the next correspondence to the Examiner.


28. Applicant is reminded that a recitation of intended utility in the preamble does not impart patentability to a composition/compound claim, but carries patentable weight in a method claim.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



D. L. Jones
Primary Examiner
Art Unit 1616

September 16, 2002